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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,740	05/18/2000	Michael S. South		9926

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 01/29/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/574,740

Applicant(s)

SOUTH ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 and 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 17, 20, 33-44 and 47-58 is/are rejected.
- 7) ☒ Claim(s) 5-8, 18-24, 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of group III (claims 1-8, 17-24, and 33-58) in paper no. 8 is acknowledged. Applicant also elected species having alkyl for group B. The traversal on the ground of no serious burden of searching is not found persuasive. The combination of B, Y⁰, and pyridinone allows for countless permutations, which require an extensive on-line search with an exorbitant number of hits. The burden of searching is clearly there.

Claims 1-8, 17-24 and 33-58 are pending for prosecution. Claims 9-16, and 25-32 are withdrawn from consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 17, 20, 33-44, and 47-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. There are several sets of definitions for B that are not recited as alternatives. For example, B is optionally hydrido, trialkylsilyl, etc., but at the same time, B is also selected from the groups consisting of cycloalkyl, heterocyclcyl, etc. Thus, it is unclear which set of definition is intended since B cannot be two things at the same time.

- b. The definition of A contains double inclusion because when A represents a single bond, it is the same as having 'rr' and 'pa' equal to 0 on the group, $(CH(R^{15})_{pa}-(W^7)_{rr})$.
- c. In the definition of Q and Y^0 , when one of the ring variables represents a covalent bond, there exists a triple bond in said ring, which is not an art-recognized ring.
- d. Claim 58 provides for the use of a compound in any one of claims 1-45, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 58 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 3. Claims 1-4, 17, 33-44, and 47-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. When Q and/or Y⁰ represent a ring having a triple bond, it is simply impossible to make since such a ring would have a configuration too constrained to allow a cyclic structure. Since such a compound cannot be made, its pharmaceutical composition and method of treatments do not have a sound basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 17, 20, and 47-57 are rejected under 35 U.S.C. 102(a) as being anticipated by **Sanderson et. al.** (WO 98/31670 – cited on the IDS). On page 54, Sanderson et. al. discloses a compound of formula III-6 (see Example III) which is embraced by the claimed formula with the following substituents:

- i. B is hydrido; A is a bond; ψ is –NH;
- ii. X is alkylthio; R² is Z⁰-Q (with Z⁰ as CH₂ and Q as hydrido);
- iii. K is CH₂; E⁰ is –C(O)NH;

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iv. Y^0 is pyridyl group substituted with CH_3 and NH_2 .

5. Claims 1, 2, 17, 20, and 47-57 are rejected under 35 U.S.C. 102(b) as being anticipated by **Sanderson et. al.** (WO 97/01338; US 5,668,289 – cited on the IDS). In Example XXXI on page 71 of WO'338, Sanderson et. al. discloses a compound which is embraced by the claimed formula with the following substituents:

v. B is alkyl group substituted with a cyclohexyl group; A is a bond; ψ is –NH;

vi. X is hydrido; R^2 is Z^0 -Q (with Z^0 as CH_2 and Q as hydrido);

vii. K is CH_2 ; E^0 is $-C(O)NH$;

viii. Y^0 is pyridyl group substituted with CH_3 and NH_2 .

In Example XIX on column 41 of US'289, Sanderson et. al. discloses a compound that is embraced by the claimed formula with the following substituents:

ix. B is an alkyl group substituted with a aryl group; A is a bond; ψ is $-NH$;

x. X is hydrido; R^2 is Z^0 -Q (with Z^0 as CH_2 and Q as hydrido);

xi. K is CH_2 ; E^0 is $-C(O)NH$;

xii. Y^0 is pyridyl substituted with CH_3 and NH_2 .

Said compounds can also inhibit thrombin formation, and ultimately treat related disorders such as those claimed herein (e.g., deep vein thrombosis, thromboembolism, etc.). Thus, at the time of the invention, one skilled in the art would have known how to make and use some of the compounds claimed herein.

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Claim Objections

6. Claims 5-8, 18-24, 45 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. A search in the relevant art did not yield elected species recited in said claims.

Information Disclosure Statement

5. The IDS of 4-19-01 and 06-05-01 apparently lists references of co-pending applications, which are not available with the instant application. Applicant is respectfully requested to submit at least the non-patent literatures.

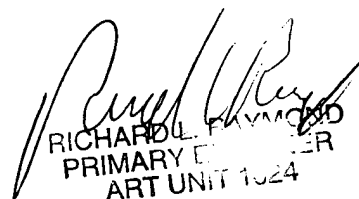
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong

January 25, 2002


RICHARD L. FARNSWORTH
PRIMARY EXAMINER
ART UNIT 1624